

## REMARKS

This is a full and timely response to the Official Action mailed June 23, 2006. It is timely in view of the Petition for Extension of Time submitted concurrently herewith. Reexamination and reconsideration of the rejections set forth therein in light of the following amendments and remarks are courteously requested.

By the foregoing, claims 20-23 and 25-26 are currently pending for the Examiner's consideration. Claim 17 was canceled without prejudice or disclaimer to its underlying subject matter. Claim 26 has been added. The subject matter of claim 26 finds basis in the Specification in original claim 20 and at p. 15, l. 21-22. Claims 20-23 have been amended by adding the clause "during intimate activities", which amendment finds basis in the Specification at p. 15, l. 21-22. Claims 20-23 and 25 have also been amended to include the phrase "substantially anhydrous". This amendment finds basis in the Specification at p. 7, l. 28 to p. 8, l. 33. The term "Maximum" has been deleted from claims 20-23 and 25 in order to clarify the meaning of the claim. The term "Energy Release Index" finds basis in the Specification at p. 13, l. 22-25.

The Office Action of June 23, 2006 objected to the specification of the disclosure because drawing Figures 7-11 were not referenced under the "Brief Description of the Drawings" Section of the specification. Brief descriptions of the drawings have been added above. These descriptions find basis in the Specification in the original drawings. No new matter has been added to the Specification.

The Office Action of June 23, 2006 provisionally rejected Claims 17, 20-23 and 25 under 35 U.S.C. 101 as claiming the same invention as that of the claims 15, 19-22 and 24 of copending Application Serial No. 10/696,939. Applicants respectfully request abeyance of this provisional rejection in view of the ongoing prosecution process. Should claims be allowed in this application or in copending Application Serial No. 10/696,939, appropriate amendment shall be undertaken to overcome this rejection. The Office Action further rejected claims 17, 20-23 and 25 on ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 15 and 19-24 of U.S. Patent No. 7,005,408.

The Office Action also rejected claims 17, 20-23 and 25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-18 of copending Application No. 10/697,383; as being unpatentable over claims 24-28 of copending Application No. 10/389,871; as being unpatentable over claims 20-35 of copending Application No. 10/390,511; and as being unpatentable over claims 15 and 19-23 of copending Application No. 11/299,884. Applicants respectfully offer to file an appropriate terminal

disclaimer in compliance with 37 CFR 1.321(c) to overcome each nonstatutory double patenting rejection should claims be allowed in this and any of the foregoing applications.

The Office Action of June 23, 2006 rejected claims 20-23 and 25 under U.S.C. 112, first paragraph, on the ground that “the specification, while being enabling for a substantially anhydrous lubricant composition comprising at least one polyol, wherein said composition increases in temperature by at least about 5° C upon exposure to moisture and which has a “Maximum”? Energy Release Index of at least about 11 mJ/mg, does not reasonably provide enablement for a substantially non-anhydrous lubricant composition” [Office Action, p. 2]. Applicants respectfully request reconsideration of this rejection in view of the foregoing amendments to the claims.

Claims 20-23 and 25 have been amend to include the phrase “substantially anhydrous” to correct an inadvertent omission of the phrase. This amendment, applicants respectfully submit, renders moot the above-mentioned rejection.

The Office Action of June 23, 2006 rejected claims 20-23 and 25 under U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The specific grounds on which this rejection was based are as follows:

Applicant's claims are deemed to be indefinite in regards to the claim limitation of: “wherein said composition increases in temperature by at least about 5°C upon exposure to moisture and which has a *Maximum* Energy Release index of at least about 11 mJ/mg...Should not the word “Maximum” be replaced with the word –Minimum— for the claims to make sense? [Office Action, p. 3]

Applicants respectfully request reconsideration of the foregoing rejection in light of the foregoing amendments to the claims and the ensuing remarks. Applicants respectfully point out that the term “Energy Release Index” is a defined term, meaning “the amount of energy released (hereinafter, “Energy Release Index”) by solubilizing the compositions of this invention” [Specification, p. 13, l. 22-25] Applicants have amended the claims to reflect this definition therein and therefore respectfully request reconsideration of the foregoing rejection.

The Office Action rejected claims 17 and 20-23 under 35 U.S.C. 102(b) as being anticipated by or, in the alternative as being rejected under 35 U.S.C. 103(a) as being obvious over JP Application Publication No. 2-311408 to Akiyama or JP Publication No. 2001-335429 or

Spanish Publication No. ES 2,074,030 to Carreras et al. or PCT Application No. WO 01/64176 to Scholz et al. The basis for this rejection is as follows:

Akiyama et al., Osamu et al., Carreras et al. and WO all directly teach anhydrous or substantially anhydrous gel or gel-like therapeutic topical compositions for use on the human body such as the skin. The said therapeutic topical compositions comprise at least one polyol, such a propylene glycol, polyethylene glycol, glycerin or the like. The thickening agent can be hydroxyethyl cellulose or the like. Additional adjuvants well known in be used in therapeutic topical compositions, such as antimicrobial agents, anti-inflammatory agents, anti-septics, pH regulators, etc., can optionally be added to said compositions. All said therapeutic topical compositions are disclosed to generate heat of solution when they are brought in contact with moisture such as water...[Office Action, p. 5]

Applicants respectfully request reconsideration of the foregoing rejection in view of the ensuing discussion.

Osamu et al describes a “gel-like makeup” [Osamu et al., ¶0001]. Osamu et al. requires the presence of “40-75% of the weight of a polyethylene glycol, 20-55% of the weight of a glycerol, and a carboxyvinyl polymer” [Osamu et al., ¶0009]. Thus, Osamu et al. **requires** the presence of a carboxyvinyl polymer, which is an anionic polymer, and suggests the use of the composition as a “makeup” material. Osamu et al. relates to a *topical* product, but does not suggest or describe the use of its “gel-like makeup” compositions on mucosal tissue. Nowhere does Osamu et al. suggest or describe a method of increasing intimacy or use of such a composition in connection with intimate activities, for treating female sexual dysfunction, vulvodynia or dysmenorrhea. Nor, as stated in the Office Action, does Osamu et al. suggest or describe the required Energy Release Index as set forth in the claims.

Akiyama et al. relates to gelatinous compositions containing “anionic polymer compounds and a water-soluble non-ionic polymer compound in a solvent whose main component is a polyhydric alcohol, and wherein the concentration of polyhydric alcohol in the solvent is 80 wt% or greater” [Akiyama et al., p. 2, l. 4-7]. Akiyama et al. indicates that the purpose of the composition is for use “as a pack or massage agent” [Akiyama et al., p. 2, l. 14]. As stated above with respect to Osamu et al., not only does Akiyama et al. not indicate the appropriate Energy Release Index of the claimed invention, it nowhere suggests or describes the methods described in the claims of increasing intimacy, treating female sexual dysfunction, treating vulvodynia or treating dysmenorrhea.

Carreras et al. describes self-heating compositions of active pharmaceutical substances for topical application. Rather than utilizing the ambient moisture present in the skin or mucosa to generate heat of solution, Carreras et al. discusses compositions that "generate heat by means of an intimate 'in situ' mixing of similar amounts of two previously separated liquid or semisolid component parts, namely an aqueous part (W) and another, organic part (O)...[Carreras et al., p. 5, l. 3-6]. In contrast to the compositions of applicants' invention, Carreras et al. requires a combinatory step in addition to that of the method of applicants' invention in order to arrive at a heated composition. Furthermore, nowhere does Carreras et al. suggest or describe the methods described in the claims of increasing intimacy, treating female sexual dysfunction, treating vulvodynia or treating dysmenorrhea.

Scholz et al. describes a cleansing gel which releases hydration heat when mixed with water. Such a cleansing gel contains surfactants [Scholz et al., col. 2, l. 33 – col. 3, l. 32], which are quite irritating, especially to the mucosal tissues. Thus, one would not look to Scholz et al. to teach the use of such compositions in intimate areas. Nor does Scholz et al. suggest or describe the methods described in the claims of increasing intimacy, treating female sexual dysfunction, treating vulvodynia or treating dysmenorrhea.

Applicants respectfully submit that because Akiyama et al, Osamu et al, Carreras et al. and Scholz et al. fail to disclose, either explicitly or implicitly, individually or in combination at least the above-noted feature recited in independent claims 20-23 and 25, the cited and relied-upon references do not anticipate these claims. Therefore, applicants respectfully request reconsideration of the rejection of claims 20-23 and 25 under 35 U.S.C. §102(b) in view of the cited patents and publications.

Claims 17 and 20-23 were rejected as being obvious over Akiyama et al., Osamu et al., Carreras et al. or the Abstract of WO 01/64176. Applicants respectfully request reconsideration of this rejection in view of the ensuing remarks.

The Office Action admits that Akiyama et al, Osamu et al, Carreras et al. and Scholz et al, fail to disclose teach or suggest a 5°C increase in temperature upon exposure to moisture and which has a Maximum Energy Release index of at least about 11 mJ/mg. Rather, the Office Action contends, without providing supporting evidence, that it would have been obvious to make compositions that meet Applicants' claim limitations requirements.

Applicants respectfully submit that the "characterization of certain specific limitations or parameters as obvious does not make Appellants' invention, considered as a whole, obvious." *Ex parte Petersen*, 228 USPQ 217, 218 (Bd. Pat. App. & Int. 1985). The specific reference or generally known facts must have existed "at the time the invention was made." *In re Merck & Co., Inc.*, 231 USPQ 375, 379 (Fed. Cir. 1986).

Applicants respectfully submit that the contention asserted within the Office Action fails to show that "obviousness" existed at the time the invention was made. More specifically, the Office Action fails to provide a suitable teaching, suggestion, inference, or motivation in the prior art to demonstrate that the limitation and advantages would have been obvious to one skilled in the art at the time the claimed invention was made.

Akiyama et al, Osamu et al, Carreras et al. and Scholz et al., fail to disclose, teach or suggest at least the above noted features of the claimed invention, and applicants submit, therefore, they do not anticipate Applicants' invention or render the invention obvious. None of the cited references would have directed one of ordinary skill in the art toward the methods set forth in applicants' claims. Therefore, applicants respectfully request reconsideration of the rejection of claims 17, 20-23 and 25 under 35 U.S.C. §103(a) in view of these patents and publications.

Claim 25 was rejected under 35 U.S.C. 103(a) as being obvious over JP Application Publication No. 2-311408 to Akiyama or JP Publication No. 2001-335429 or Spanish Publication No. ES 2,074,030 to Carreras et al. or PCT Application No. WO 01/64176 to Scholz et al. Applicants respectfully request reconsideration of this rejection in view of the ensuing discussion.

Claim 25 recites a method of treating dysmenorrhea. The method comprises applying a composition comprising of at least one polyol, and an anti-inflammatory agent. The composition increases in temperature by at least about 5°C upon exposure to moisture and has a Energy Release Index of at least about 11 mJ/mg to a tampon and inserting the tampon vaginally.

As stated above, none of Akiyama et al, Osamu et al, Carreras et al. and Scholz et al., discloses, teaches or suggests a composition comprising at least one polyol and an anti-inflammatory agent. Accordingly, one of ordinary skill in the art at the time the invention was made would not have been led to the claimed method of use in view of the teachings of Akiyama

et al, Osamu et al, Carreras et al. and Scholz et al. Reconsideration of this rejection is therefore respectfully requested.

Claims 17, 20-23 and 25 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over U.S. Patent No. 7,005,408 to Ahmad et al. Applicants respectfully request reconsideration of this rejection in view of the ensuing discussion.

Applicants respectfully submit that 35 U.S.C. 102(e) provides as follows:

...the invention was described in (1) *an application for patent*, published under section 122(b), *by another* filed in the United States before the invention by the applicant for patent or (2) a patent granted on *an application for patent by another* filed in the United States before the invention by the applicant for patent...[35 U.S.C. 102(e)](emphasis added)

Applicants respectfully point out that 35 U.S.C. 102(e) requires that the application over which the current application is being rejected be the application of *another*, i.e., another inventive entity. Applicants respectfully submit that U.S. Patent No. 7,005,408 and the above-captioned application have the same inventive entity. Thus, 35 U.S.C. 102(e) should not be applicable in this situation. Applicants therefore respectfully request reconsideration of this rejection.

For the foregoing reasons, applicants respectfully submit that the above-captioned application is now clearly in condition for allowance. Accordingly, favorable reconsideration of the above remarks and an early Notice of Allowance are courteously solicited. If the Examiner has any comments or suggestions that could place this application in even better form, the Examiner is requested to telephone the undersigned Attorney at the below-listed number.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 10-0750.

Respectfully submitted,

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